

REMARKS

Claims 1-6, 10-11 and 16 were rejected under 35 U.S.C. § 103(a) as unpatentable over LaHann et al. (U.S. Patent 4,546,112) in view of Michaels et al. (U.S. Patent 3,843,780). Applicant traverses this rejection.

Fundamental to LaHann is the use of capsaicin as an active for preventing or reducing depilatory caused dermal irritation. Capsaicin is used at relatively low levels. These small amounts indicate that the material is an active substance chemically interacting with receptors in the skin. Carriers for this active substance are reported to be lotions, creams, solutions and gels. All of these forms include very large amounts of water. None of the different forms has more than about 50% of emollients some of which are lipophilic materials.

In contrast to a chemically active substance, the present invention provides a skin pretreatment composition operating in a physical manner. Lipophilic materials are believed to coat the skin thereby serving as a blanket protection against the subsequent application of caustic depilatory. The depilatory "sees" the keratin fibers but is shielded by the lipophilic materials from contact with underlying skin.

Thus, the present invention differs in concept and composition from that of the primary reference. LaHann attenuates irritation through the chemical means of capsaicin. By contrast, applicant utilizes a physical blanket of lipophilic materials to separate the harsh depilatory from the skin but not from the keratin fiber. Applicant employs from 90 to 100% of lipophilic materials in the pretreatment composition. LaHann does not appreciate the physical approach nor suggests using extremely high

levels of lipophilic materials. For these reasons, LaHann does not render the claims *prima facie* obvious.

In the Final Office Action, the Examiner highlights Example 3. Therein varying amounts from 1% to 8% capsaicin are applied to skin in some instances before and in some after depilation. The applied formula dissolves capsaicin in an isotonic saline solution containing 48% ethyl alcohol and 4% Tween 80 (surfactant emulsifier). Applicant notes that at least 90% if not more of the applied formula is other than lipophilic material. This contrasts sharply with the present claims. The active ingredient of capsaicin is utilized at a top level of only 8%. This contrasts with the extremely large amounts of lipophilic material utilized for purposes of the presently claimed invention.

Capsaicin as utilized by LaHann is a dermatologically active chemical. By contrast, applicant's lipophilic material such as mineral oil is not dermatologically active. Applicant utilizes the lipophilic material composition for its coating properties. For this reason, it is inappropriate to compare capsaicin or its quantities with those of the claimed lipophilic material composition.

Michaels et al. was introduced for teaching mineral oil as a pretreatment composition in shaving. There is a significant difference between shaving and depilatory treatment. The former utilizes a sharp blade while the latter is chemical. Methods and compositions which are useful against sharpened blades would not be obvious substitutes for the quite different depilatory treatment. Those skilled in the art would not be likely to employ the teachings focused on razor technology into the depilatory arts.

Yet even if the LaHann and Michaels et al. references were combinable, the combination would still not provide a prima facie case of obviousness. The compositions of Michaels et al. utilize mineral oil at levels of maximum 85% by weight. See column 1, line 15. The remainder of the formula is anhydrous lower aliphatic monohydric alcohols. Aliphatic alcohol is defined as having from one to four carbon atoms, such as methanol, ethanol, propanol and butanol. See column 2, lines 39-42. These alcohols are not lipophilic materials.

Several times in her Final Office Action, the Examiner refers to Michaels as teaching "using up to 87% of lipophilic materials". Applicant is unable to find any reference to "87%" lipophilic materials. The Examiner may wish to identify the section of Michaels in which this percentage appears.

Essentially the Examiner argues that the actually reported 75-85% disclosed mineral oil range is not so different from applicant's claimed 90-100%. Applicant disagrees. There actually is a difference both in kind and quantity. With respect to the latter, Michaels teaches away from anything in excess of 85%. The reference requires from 15 to 25% of anhydrous lower aliphatic monohydric alcohol. See column 1 (lines 16-17) and column 2 (lines 36-45). The anhydrous alcohol is present "to assist in the deposition of the mineral oil as a film on the skin". Those skilled in the art reading this reference would find a minimum of 15% anhydrous alcohol to be essential. This teaches away from the at least 90% of the present claims. Note also that lower aliphatic monohydric alcohols are hydrophilic rather than lipophilic; the alcohol changes the character of the mineral oil containing composition. Again this leads away from the present invention which seeks to apply a protective lipophilic coat to skin prior to depilation.

There also is a difference in kind. The mineral oil containing composition of Michaels is intended to lubricate the skin, the hair and the razor to increase comfort level during shaving. See column 1 (lines 65-67). By contrast, applicant utilizes the lipophilic material composition as a protective coating against the harsh chemicals of depilatories. There is no functional necessity in depilation to lubricate the skin or lubricate the hair or lubricate the nonexistent razor. Thus, the 90% lipophilic material composition has a function much different than that described by Michaels.

Cited in support of the Examiner's position was In re Aller, 105 USPQ233 (CCPA 1955). The case was selected for stating that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." The Examiner applied this to the present claims reciting 90-100% lipophilic materials. Yet unlike the present rejection of LaHann in view of Michaels, In re Aller was a rejection over a single reference showing all elements except the claimed concentration range. The skilled chemist for In re Aller needed only to slightly adjust process temperature and reactant concentration. Yet with the present claims, the skilled chemist must not only increase lipophil concentration but must transplant this adjusted value into a depilatory system found in a different reference. Especially in a situation where combination of such references is questionable, altering the concentration of one element is not obviously straightforward experimentation.

Claim 16 identifies the skin pre-treatment composition as one which "consists essentially of" the 90-100% lipophilic material. The transitional phrase of "consists essentially of" is construed by the Examiner as equivalent to "comprising". The Examiner supports this view "because there is no disclosure in the specification or claims that using 90-100% is the basic novel characteristic of the present invention."

Applicant draws attention to the comparative experiments under Example 1 and 2. Pretreatment was conducted with 100% mineral oil in both of those clinical trials. See paragraph [00040] and [00045], respectively.

Another questionable rejection was the Examiner's view that the claim 16 phrase of "the lipophilic materials protecting skin from redness/erythema" was an inherent result. The Examiner further stated that "the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." This was cited from Ex parte Obiaya, 227 USPQ 58 (Bd. Pat. App. & Inter. 1985).

Applicant observes that Ex parte Obiaya first requires the establishment of a *prima facie* case of obviousness predicate to the dicta. The present Examiner has not yet established a *prima facie* case of obviousness. Neither of the references teach a pre-treatment with the extremely high levels of lipophilic materials as presently claimed.

A combination of LaHann in view of Michaels et al. would not render the present invention obvious. Neither of the references discloses upwards of 90% lipophilic materials. Further, there simply is no suggestion or incentive for incorporating mineral oil at even 85% as disclosed by Michaels et al. into the primary reference. Irritation caused by razor attack is much different than the effect of chemical burn.

Claims 7, 12-15 and 17 were rejected under 35 U.S.C. § 103(a) as unpatentable over LaHann in view of Michaels and Orlow et al. (U.S. Patent 6,749,840 B2). Applicant traverses this rejection.

Independent claim 7 recites a kit for removal of hair from an area of skin. The kit includes a skin pre-treatment product which comprises a pre-treatment composition comprising 90-100% lipophilic materials. Additionally present is a depilatory product comprising a composition with an effective amount of a keratin degrading agent effective to chemically react with hair and allow wipe away removal. Instructions are included in the kit on how to apply the pre-treatment product and then the depilatory product over a selected area of skin.

LaHann does not disclose a kit. Neither is there any disclosure of a pre-treatment composition that comprises any substantial amount of lipophilic materials. Indeed, the comparative examples at best hint at 50% maximum "emollient" with the balance being water. Any arguably pre-treatment compositions among the four Examples have greater than 90% hydrophilic rather than lipophilic material (i.e. water). LaHann uses a small amount of capsaicin as an active agent to control dermal irritation. This is a much different method and pre-treatment composition from the coating and highly lipophilic pre-treater of the present claims.

Michaels has nothing to do with depilatories. This is a disclosure concerned with attenuating the trauma of a shaving blade. Depilatory chemicals penetrate the hair follicle and react with the keratin. These are very harsh conditions. By contrast, shaving is a mechanical irritation and much more of a surface phenomena. Chemical irritation in the aftermath of depilation is different than irritation generated through a steel blade. Michaels utilizes a mineral oil composition to lubricate the cutting blade, the hair target and the skin. There is no suggestion that the concept of lubrication would be appropriate for depilation. Indeed, the skilled chemist would conceptually avoid lipophilic materials as pre-treaters. The reason would be concern that a lipophilic coating over the hair would prevent the depilatory chemical from efficiently reacting therewith. Yet applicant was quite surprised that lipophilic materials such as mineral oil

did not significantly inhibit the depilatory chemical reaction. But there was an improvement in lowering skin irritation. These were unexpected results.

Orlow was introduced as disclosing that personal care compositions are packaged with printed instructions as a label or package insert directing use of the composition.

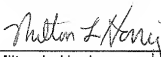
Deficiencies of the primary references are not remedied by Orlow. Not only do the claims require instructions for the kit but the instructions must direct a user to apply the skin pre-treatment product prior to application of the depilatory. These instructions are not provided by Orlow. Neither does this reference disclose use of relatively high levels of lipophilic material as a skin pre-treatment composition. For these reasons, the claims are not *prima facie* obvious over the combination of art.

Claims 8 and 9 were rejected under 35 U.S.C. § 103(a) as unpatentable over LaHann, Michaels and Orlow and further in view of Syed et al. (U.S. Patent 5,756,077). Applicant traverses this rejection.

Syed et al. does not remedy the basic deficiencies of the combination of other references. There is no disclosure of utilizing as a pre-treatment the composition comprising at least 90% of lipophilic materials. The reference is directed at hair coloring rather than to depilation. The combination of art would not render the claims *prima facie* obvious.

In view of the foregoing comments, applicant requests the Examiner to reconsider the rejection and now allow the claims.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Milton L. Honig", is written over a horizontal line.

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